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| 10/570,013 | 02/28/2006 | Kei Yoshida | PREZP102US | 5278 |
| <div>23623 7590 10/22/2009</div> <div>TUROC & WATSON, LLP</div> <div>127 Public Square</div> <div>57th Floor, Key Tower</div> <div>CLEVELAND, OH 44114</div> | | | | |
| <div>EXAMINER</div> <div>KUMAR, SHAILENDRA</div> | | | | |
| <div>ART UNIT PAPER NUMBER</div> <div>1621</div> | | | | |
| <div>NOTIFICATION DATE DELIVERY MODE</div> <div>10/22/2009 ELECTRONIC</div> | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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In re Application of :
Yoshida et al. :
Serial No.: 10/570,013 :Decision on Petition
Filed: 28 February 2006 :
Attorney Docket No.: PREZP102US :

This letter is in response to the petition filed under 37 C.F.R. § 1.144 filed on May 19, 2009 requesting reconsideration of the lack of unity requirement. The delay in acting upon this petition is regretted.

BACKGROUND

This application was filed as a national stage application under 35 USC 371 and as such, is eligible for unity of invention practice.

On 25 May 2008, the examiner divided claim 1-21 into 8 Groups as follows

- Group I, claims 1-8, 17, and 18, drawn to compounds;
- Group II, claim 9, drawn to compounds;
- Group III, claim 10, drawn to compounds;
- Group IV, claim 11, drawn to compounds;
- Group V, claims 12-14, drawn to process of making compounds;
- Group VI, claim 15, drawn to compounds;
- Group VII, claim 16, drawn to compounds;
- Group VIII, claims 19-21, drawn to a method of using compounds.

As evidence of lack of special technical feature which makes a contribution over the prior art, the examiner referred to the search report of PCT/JP04/012416, which cited references showing that

the genus of claim 1, as it was pending in the PCT application, is not novel. The examiner also required applicants to elect a species of compound from the examples of the specification.

On 25 April 2008, applicants filed a bona fide response which elected Species I with traverse.

On 22 July 2008, the Examiner mailed applicants a Notice of Non-Responsive Amendment, even though no amendment had been filed.

On 11 September 2008, applicants elected, with traverse, Group I and the compound 130. Applicants indicated that claims 1-14 and 16-21 read upon the elected species.

On 19 December 2008, the examiner mailed to applicants a non-final Office action. The examiner addressed the traversal and made the requirements final. Claims 9-16 and 19-21 were withdrawn as being directed to non-elected invention. Claims 1-8 and 17-18 were examined "to the extent that they read on the elected species and closely related compounds encompassing the elected species." The examiner then stated that "the elected species is free of the prior art. Claims 1-8 are objected to as containing subject matter that is drawn to the non-elected subject matter, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims encompassing the elected species and closely related species."

On 24 February 2009, applicants filed an Information Disclosure Statement.

On 19 May 2009, applicant submitted the petition currently under review.

DISCUSSION

The petition and file history have been carefully considered.

I. Concerning Lack of Unity Amongst Groups I, II, III, IV, VI and VII:

The examiner has taken the position that the compounds of Formulas 1-4, 8 and 9 lack unity of invention, however, this is not convincing because no specific prior art was identified and applied to the product claims as pending in this application. For this reason, unity is assumed to be present amongst the product claims.

II. Concerning the lack of unity between product (I, II, III, IV, VI and VII) and process (V and VIII) inventions:

Groups 5 and 8 are methods of making and using the compounds of Group I. Because no prior art has been cited on the elected invention of Group I, the method of making and using the elected compound necessarily share a same or corresponding special technical feature with Group I.

III. Concerning the requirement to elect a species for examination:

In order to require an election of species amongst embodiments of a Markush claim in a national stage filing of a PCT application, the examiner should have followed the guidance provided by the International Search and Preliminary Examination Guidelines published January 2004, relevant parts of which are provided below:

The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

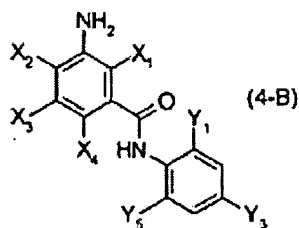
(B)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words “significant structural element is shared by all of the alternatives” refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

In paragraph (B)(2), above, the words “recognized class of chemical compounds” mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

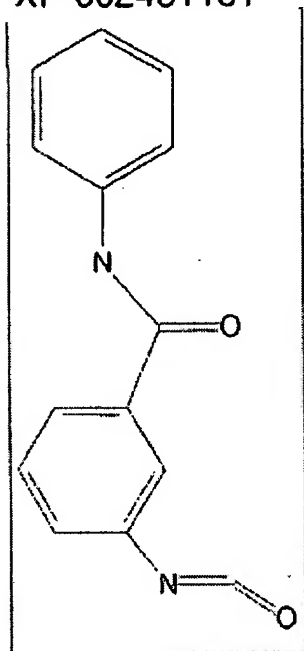
In this instance, the examiner has not established that the species are not of a similar nature.

Here, the Compounds of Formulas 1, 2, 3, 4, 8 and 9 will be analyzed for unity of invention. All the compounds require a benzamide ring. This is a not a substantial structural feature because it is small portion of the molecule. The variables attached to the benzamide rings may be quite a bit larger than the benzamide ring. See for example, taken in view of the many diverse and large structures which could be attached to the benzamide ring of Compound 4-B from page 167 of the specification:



Moreover, a benzamide ring portion of the molecule does not make a contribution over the prior art. Prior art reference, XP-0002431161, shows Beilstein registry number 2733469 for a compound that contains a benzamide ring.

XP-002431161



For these reasons, product does not share a general inventive concept and the election of species requirement was justified.

IV. Concerning the extent of examination required for a Markush claim:

The examiner has limited the scope of the claims under examination to the elected species and closely related species. This is problematic for three reasons.

First, it is unclear which closely related species has or have been examined. The Office action only addresses the merits of the elected species. There is no rejection or, conversely, indication of allowability for any closely related species. The “closely related species” are not identified.

Second, the examiner objects to claims for reciting non-elected species- which would presumably include both the closely related species which apparently have been examined.

Third, 35 USC 121 permits the Office to require an election of species for prosecution on the merits, to which the claims shall be restricted if no generic claim is finally held to be allowable. Maintaining a restriction requirement amongst species is only proper if it is be predicated upon a rejection under 35 USC 101, 102, 103 or 112 1st paragraph. In this instance, because there are no outstanding rejections, the examiner should have followed practice set forth in MPEP 803.02 and examined a second and/or subsequence species in order to determine the patentability of the markush claim.

However, this was not done. In the non-final Office action mailed December 19, 2008, the examiner indicated that the elected species was free of the prior art. MPEP § 803.02 states in part:

“...should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *nonelected species*, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species.”

V. Concerning the objection to the claims for containing non-elected subject matter or for containing allowable subject matter but depending upon a non-allowable claim:

Finally, it is noted that the objection of claims 1-8, 17, and 18 for reciting non-elected subject matter is improper. The claims are written using Markush format. In view of the examination practice for Markush claims (MPEP 803.02), Applicants are entitled to retain non-elected subject matter recited in the alternative of a Markush claim. Also, in view of linking claim practice (MPEP 809) and rejoinder practice (MPEP 821.04), applicants are entitled to retain linked inventions which are encompassed by a linking claim and species as encompassed by a generic claim. Moreover, the requirement to amend claim 1 to include all the limitations of the independent and intervening claims is problematic, given that claim 1 is an independent claim.

VI. Concerning the Notice of Non-Responsive Amendment mailed 22 July 2008:

Because Applicants original election filed 25 April 2008 was a bona fide response and because there was no amendment accompanying the election, the paper mailed on 22 July 2008 should have been entered into the file as a miscellaneous communication instead of a Notice of Non-Responsive Amendment.

DECISION

The petition is **GRANTED-IN-PART** for the reasons set forth above.

The lack of unity determination between Groups I-VIII is withdrawn.

Should the examiner find prior art on a second or subsequence species, per MPEP 803.02, the election of species requirement would be maintained.

The Office action of 19 December 2009 is withdrawn as incomplete, because there is no rejection under 35 USC 101, 102, 103 or 112 over the elected species, nor is there any rejection under 35 USC 101, 102, 103 or 112 over a second or subsequent embodiment in Markush claim, nor are claims encompassing the elected invention indicated as in condition for allowance. Moreover, the methods of making and using the elected product have not been examined.

The objection of Claims 1-8 and 17-18 for reciting non-elected subject matter is withdrawn.

Applicants response filed 25 April 2008 was bone fide. The Notice of Non-Responsive Amendment mailed 22 July 2008 has been re-indexed in PALM as a Miscellaneous Letter, and it should not be used to negatively impact applicants Patent Term Adjustment, should this application go on to issue.

The application will be forwarded to the examiner for consideration of the papers filed 24 February 2009 and 19 May 2009 preparation of a supplemental non-final Office action consistent with this decision, in which the claims 11-21 will be examined, per guidance in MPEP 803.02 and 821.04(b).

Any request for reconsideration should be filed within TWO (2) months of the mail date of this decision.

Should there be any questions about this decision, please contact Quality Assurance Specialist Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-0512 or by facsimile sent to the general Office facsimile number, 571-273-8300.



Remy Yucel
Director, Technology Center 1600